

REMARKS

It is respectfully requested that the present Amendment be entered into the Official File in view of the fact that the Reply automatically places the application in condition for allowance. It is also noted that claim 10 has been added and claim 8 has been canceled. Therefore, one claim has been added wherein another claim has been canceled. In other words, the same number of claims are still pending. Thus, the present Amendment is believed to be in proper form for placing the application in condition for allowance.

In the alternative, if the Examiner continues with the rejections of the present application, it is respectfully requested that the present Amendment be entered for purposes of an Appeal.

This reply is being timely filed. A Notice of Appeal was filed on February 13, 2007.

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims.

Status of the Claims

In the present Reply, claim 10 has been added. Also, withdrawn claim 8 has been canceled without prejudice or disclaimer of the subject matter contained therein. Further, claims 3 and 4 are withdrawn from consideration. Thus, claims 1-7 and 9-10 are pending in the present application.

No new matter has been added by way of this new claim. New claim 10 has support in originally-filed claims 1 and 2, as well as in other parts of the specification, such as the page 3, last paragraph and ABP118 which is a "proteinaceous compound" described at page 8, line 6.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues Under 35 U.S.C. § 112, Second Paragraph

Claims 1-2 and 5-7 stand rejected under 35 U.S.C. § 112, second paragraph, for various reasons related to indefiniteness (see pages 2-3 of the Office Action). Applicants respectfully traverse.

With respect to claim 1 and the recitation of “the inhibitory properties of said strain and secretory products thereof being maintained,” the Examiner states that the previous arguments have been considered but that “there is no clear correlation in the invention as claimed between ‘secretory products’ and the claimed ‘antimicrobial agent’” (see page 2, lines 4-6 from the bottom of the Office Action). Applicants respectfully disagree.

Applicants note page 34, starting at line 30 of the present specification. The instantly claimed antimicrobial agent is secreted by *Lactobacillus salivarius*, and thus can clearly be described as a secretory product (see page 32, lines 23+) and as an antimicrobial agent. Further, the strain of *Lactobacillus salivarius* does secrete an antimicrobial agent, more specifically a bacteriocin. The antimicrobial agent is secreted into cultured growth media. The antimicrobial activity in the cultured media is produced and secreted by growing *Lactobacillus salivarius* cells. This latter feature is embraced by instantly pending claim 1 (“An isolated or purified antimicrobial agent obtained from a strain of *Lactobacillus salivarius*”).

Further, the terms antimicrobial agent, proteinaceous compound, antibacterial protein and bacteriocin can all be used to describe the product secreted by the strain of *Lactobacillus salivarius* with the indicated characteristics. Applicants also herein submit an article by Sarah Flynn *et al.* ("Characterization of the genetic locus responsible for the production of ABP-118, a novel bacteriocin produced by the probiotic bacterium *Lactobacillus salivarius* subsp. *Salivarius* UCC118," *Microbiology*, Vol. 148, pp. 973-984 (2002)), wherein one of the co-authors is co-inventor Kevin Collins. The product ABP118 has been clearly referred to as a bacteriocin in later publications determining its exact genetic makeup. One of those publications includes the *Microbiology* (2002) article (see, e.g., the Abstract on page 973). Applicants also note that the term "antimicrobial" appears on page 981 of *Microbiology* (2002), wherein the word "antimicrobial" is used as a noun.

Thus, there is sufficient correlation in the invention as claimed between the products being secreted (which includes the antimicrobial agent) and the recited antimicrobial agent.

With regard to claim 2, the Examiner questions several terms therein.

Regarding "apparent" molecular weight, Applicants note that this is an acceptable term in the art. This is because molecular weight determination carried out by ultrafiltration (see page 41, lines 24-29 of the present specification) is a crude methodology (versus, for example, SDS-PAGE determinations). Ultrafiltration is a very common methodology for initial purification of proteins into sized fractions. Applicants also note page 9, lines 18-20 of the present specification. Thus, the term "apparent molecular weight" is an acceptable term, and thus has a definite and clear meaning to one of skill in the art.

Regarding “sensitivity,” “resistance” and the “wide pH range” in claim 2, Applicants respectfully traverse. The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. § 112, second paragraph. *See Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 221 USPQ 568, 573-74 (Fed. Cir. 1984) (court explaining that the specification must be reviewed as to providing some standard for measuring that degree). The issue for terms of degree is whether or not one having ordinary skill in the art can understand what is being claimed by the terms “sensitivity,” etc., in light of the specification. Here, the disputed terms are clear to one of skill in the art, and even supported by the present specification containing considerable experimental data (which the skilled artisan would read). Applicants also note the pH range disclosed at page 44, line 9 of the present specification. Further, one of skill in the art would clearly understand that the present invention survives over a wide range of pH, such as 2.0 (page 20, line 10) and 6.0 (page 20, line 15). Thus, pending claim 2 fully complies with the provisions of 35 U.S.C. § 112, second paragraph.

Reconsideration and withdrawal of these rejections are respectfully requested.

Issues Under 35 U.S.C. §§ 102(b) and 103(a)

Claims 1, 2, 5-7 and 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by K. Arihara *et al.* (“Salivacin 140, a novel bacteriocin from *Lactobacillus salivarius* subsp. *salicinius* T140 active against pathogenic bacteria,” *Letters in Applied Microbiology*, Vol. 22, pp. 420-424 (1996); hereinafter “Arihara”) (see pages 6-7 of the Office Action). Further, claims 1, 2, 5-7 and 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative,

under 35 U.S.C. § 103(a) as obvious over B. ten Brink *et al.* ("Antimicrobial activity of lactobacilli: preliminary characterization and optimization of acidocin B, a novel bacteriocin produced by *Lactobacillus acidophilus* M46," *Journal of Applied Bacteriology*, Vol. 77, pp. 140-148 (1994); hereinafter "ten Brink") (see pages 7-8 of the Office Action).

Applicants respectfully traverse, and request reconsideration and withdrawal of these rejections.

Applicants have reviewed the Examiner's comments that are in response to Applicants' previously submitted arguments. The Examiner refers Applicants to how the claims are directed to antimicrobial agents (see, e.g., page 4, lines 8-9 of the Office Action), how adherence of the bacterial strains and site of isolation are not material (see, e.g., page 5, first two paragraphs of the Office Action) and then states Applicants have not proven patentable distinctions over the cited references. Applicants respectfully disagree as (objective) evidence has been provided to sufficiently rebut the instant prior art rejections.

In particular, Applicants respectfully submit that paragraphs 8, 10 and 14-17 of the O'Mahoney Rule 132 Declaration (submitted with last reply dated July 6, 2006) are relevant. For the Examiner's convenience, these portions of the O'Mahoney Declaration are enclosed. Paragraphs 14-15 of the same Declaration explain features and properties of the present invention that are absent in the cited references. Paragraphs 8 and 10 show why Arihara *et al.* fails to disclose the present invention; paragraphs 16-17 show why ten Brink *et al.* fails to disclose the present invention.

As can be seen, despite the Examiner's assertion that site of isolation does not matter, the source of the microorganism does matter since the properties thereof are different. Further,

while the Examiner refers to the claimed antimicrobial agent, the instantly claimed strain of *Lactobacillus salivarius* does secrete an antimicrobial agent (also claimed). Applicants also note that other properties are instantly claimed, and such claimed features are absent in the cited references.

The Examiner states that the Arihara strain also has “bacteriocins-like properties” (see the sentence bridging pages 3-4 of the Office Action). However, Applicants note that this does mean the Arihara strain has the same properties as instantly claimed. The mentioned Rule 132 Declaration is evidence of this. Also, Applicants note the discussions in the submitted *Microbiology* (2002) paper, wherein this article describes the properties of ABP-118. For instance, in the “Discussion” section (see the paragraph bridging pages 981-982), the authors state: “ABP-118 is an intriguing broad-spectrum antimicrobial, since it is capable of inhibiting a number of food borne and medically significant pathogens, including *Bacillus*, *Listeria*, *Enterococcus* and *Staphylococcus* species, without an apparent antagonistic activity towards related LAB strains. . .” Any assertion regarding the properties of Arihara does not equate to the properties of the claimed antimicrobial.

In response to the Examiner’s concern that the USPTO is not equipped to manufacture products (citing M.P.E.P. § 2113; see the bottom of page 4 of the Office Action), Applicants note that the mentioned Rule 132 Declaration provides the needed evidence and should address the Examiner’s concern regarding testing. The Arihara strain is also discussed in the same Declaration. Reconsideration is respectfully requested in view of the Rule 132 Declaration contents.

Accordingly, under *Verdegaal Bros v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991), these rejections have been overcome as there is no disclosure of all claimed features in either Arihara *et al.* and/or ten Brink *et al.* Thus, Applicants have sufficiently rebutted the instant rejections. Reconsideration and withdrawal of all rejections are respectfully requested.

Conclusion

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez, Reg. No. 48,501, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Application No. 10/603,865

Docket No.: 1377-0188P

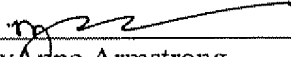
Art Unit 1651

After Final Office Action of August 14, 2006

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: April 4, 2007

Respectfully submitted,

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Attachment:

- Paragraphs 8, 10 and 14-17 of the O'Mahoney Rule 132 Declaration (first submitted with reply dated July 6, 2006)
- Sarah Flynn *et al.*, "Characterization of the genetic locus responsible for the production of ABP-118, a novel bacteriocin produced by the probiotic bacterium *Lactobacillus salivarius* subsp. *Salivarius* UCC118," *Microbiology*, Vol. 148, pp. 973-984 (2002).